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EXAMINER

CHRISTIAN, MARJORIE ELLEN

ART UNIT

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1797

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Response to Amendment

1. The amendment filed 4/29/9 has been entered and fully considered.
2. Claims 1, 3-15 are pending and have been fully considered.

Claim Rejections - 35 USC § 103

3. **Claims 1, 3-6, 12, 15 are rejected under 35 USC 103 (a) as being obvious over US Patent No. 6,156,002, POLASCHEGG et al. (hereinafter POLASCHEGG) in view of US Patent No. 6,139,748, ERICSON et al..**

As to Claims 1, 4, 15, POLASCHEGG discloses an apparatus for hemodialysis (Fig. 1), comprising a conduit in which a dialysis infusion fluid is intended to flow (10), comprising a measurement unit (172) for measuring at least one substance in said fluid by measuring the influence on a polarized beam of light transmitted through the fluid (C7/L1-14, Claim 16), where the concentration of said substance above 100g/L is the material worked upon and does not limit the apparatus. As it has been held that “expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim.”. Furthermore, “[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims.”.

POLASCHEGG does not appear to expressly disclose that the measurement unit measures the substance before fluid is mixed with other matters. However, ERICSON discloses a plurality of inlets for different matters (Fig. 1, Refs. 3-5), said different

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matters being mixed with each other (2) after being introduced via said inlets (3-5). It would be obvious to measure the concentration of the substances with the sensor of POLASCHEGG prior to being mixed with other different matters introduced via different inlets as it has been generally recognized that to shift location of parts when the operation of the device is not otherwise changed is within the level of ordinary skill in the art. *In re Japikse*, 86 USPQ 70; *In re Gazda* 104 USPQ 400.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the hemodialysis apparatus of POLASCHEGG to include the plurality of inlets and mixing of ERICSON. The motivation would have been to provide concentration of glucose that mimics normal blood concentrations (C1/L17-28). Further, it would be obvious to one of ordinary skill in the art to use the teachings of these references to arrive at applicant's invention because it produces no more than predictable results. See *KSR Int'l. v. Teleflex Inc.*, 127 S. Ct. 1727, 1732, 82 USPQ2d 1385, 1390 (2007). "it is commonsense that familiar items have obvious uses beyond their primary purposes, and a person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle". "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results". Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

As to Claim 3, ERICSON discloses a first inlet (3) for introducing the fluid to be measured into the apparatus (2) and it would be obvious to a person having ordinary

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skill in the art to measure the substance with the measurement unit of POLASCHEGG configured such that it measures the concentration before being mixed in the apparatus (2) with any other different matters introduced via another of said plurality of inlets (4, 5), as it is implicit that the concentration of the substance is measured (known) prior to being mixed.

As to Claims 5-6, POLASCHEGG discloses the measurement unit is designed to measure the concentration of glucose (C7/L1-5).

As to Claim 12, POLASCHEGG discloses a container housing a fluid (186), wherein the container is connected to the apparatus to allow the fluid housed in the container to be fed to the apparatus (Fig. 3), and said measurement unit (172) is arranged to measure the concentration of said substance in the fluid fed from the container.

4. **Claims 7-11 are rejected under 35 U.S.C. 103(a) as being obvious over US Patent No. 6,156,002, POLASCHEGG et al. in view of US Patent No. 6,139,748, ERICSON et al. and US Patent No. 5,457,535 SCHMIDTKE et al..**

As to Claim 7, POLASCHEGG (in view of ERICSON) discloses measuring the concentration of a substance in a hemodialysis apparatus as shown in the 103(a) rejection of Claim 1. POLASCHEGG does not appear to explicitly disclose generating a warning if the measured concentration does not fulfill a predetermined requirement. However, SCHMIDTKE discloses means arranged to generate a warning signal if the

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measured concentration of said substance in said fluid does not fulfill a predetermined requirement (SCHMIDTKE, Claim 10, Ref. 39a).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the optical sensor of POLASCHEGG to include the warning signal of SCHMIDTKE. The motivation would have been to accurately measure the concentration of optically active substances (C1/L52-58) and avoid exceeding a threshold value of detected stray light which interferes with measurement (C7/L23-27). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

As to Claim 8, SCHMIDTKE discloses a partly transparent conduit in said apparatus (C3/L32-37), configured to carry the fluid to be measured (C3/L38-50), wherein said measurement unit is configured to produce a polarized beam of light that is passed through the fluid to be measured at the conduit (Abstract).

As to Claim 9, SCHMIDTKE discloses said measurement unit is arranged to provide a plane-polarized beam of light (Abstract, Refs. 1, 21, 23, 31, 36).

As to Claim 10, SCHMIDTKE discloses a measurement device to measure an entity (Abstract), said entity indicating the angle at which the plane of polarization of said polarized beam of light has rotated when the polarized beam of light has passed through the fluid (C5/L4-31, Ref. 39).

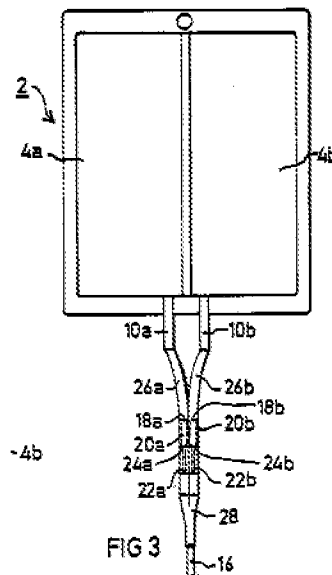
As to Claim 11, SCHMIDTKE discloses a light intensity detector (54, 64).

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5. **Claims 13-14 are rejected under 35 USC 103 (a) as being obvious over US Patent No. 6,156,002, POLASCHEGG et al. in view of US Patent No. 6,139,748, ERICSON et al. and WO95/08299 TOBE et al..**

As to Claim 13, POLASCHEGG discloses the container of fluid to be measured as shown in the 102(b) rejection of Claim 12. POLASCHEGG does not appear to expressly disclose the container includes first and second compartments. However, TOBE discloses the container (Fig. 3, Ref. 2) includes first (4a) and second compartments (4b) having contents, the contents of the compartments being mixed before the fluid leaves the container (28).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the container of fluid of POLASCHEGG to include the first and second compartments of TOBE. The motivation would have been to have an assembly that can easily and safely mix liquids in a single operation (Pg. 2, Lines 27-31). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.



As to Claim 14, TOBE discloses the container is a flexible fluid bag (Pg. 3, Line 7).

Response to Arguments

6. Applicant's arguments filed 4/29/9 have been fully considered but they are not persuasive in view of the new grounds of rejection necessitated by amendment.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: WO2004/070323, HALLSTADIUS et al. as it discloses a sensor device for measuring concentrations in fluid flow.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJORIE CHRISTIAN whose telephone number is (571)270-5544. The examiner can normally be reached on Monday through Thursday 7-5pm (Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1797

MC